

REMARKS

Claims 5 and 9 have been cancelled, without prejudice.

Claims 1-2 have been amended to recite "cultivating a microorganism ... at a pH in the range of about 4.0 to about 9.0 and in a temperature range from about 13°C to about 36°C for about 1 to about 5 days" Support for these amendments is found in original claim 5 and in the specification at, for example, page 3, lines 16-21 and Examples 1-3. See *In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01 (o) and (l).

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments is respectfully solicited.

§112, First Paragraph Rejection:

Enablement

Claims 1-10 have been rejected solely under 35 U.S.C. §112, first paragraph, for lack of enablement. (Paper No. 20070531 at 3). In making the rejection, the Examiner acknowledged that the specification "[is] enabling for the specific examples" (*Id.*).

The Examiner, however, asserted that "the specification ... does not reasonably provide enablement for the claims based on the prior art U.S. Publication 20010026933 published October 04, 2001 which Application is a division-of US application 09/203628, filed December 1, 1998, US Patent No. 6242233." (*Id.*). The Examiner further asserted that "[t]he specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and practice the invention commensurate in scope with these claims since the reference ...

cultures the same microorganism in the presence of substrate(s) within the scope of the claimed subject matter with the **same** pH, time and temperature but does not produce and recover Vitamin C.” (*Id.*) (emphasis added). The Examiner then contended that “[a]pplicant is required to insert the conditions which produces the Vitamin C directly from the reaction mixture.” (*Id.* at 4).

Initially we note, it is the Examiner’s burden to demonstrate that a specification is not sufficiently enabling. *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971). To carry his/her burden, the Examiner must identify and clearly articulate the factual bases and supporting evidence that allegedly establish that undue experimentation would be required to carry out the claimed invention. *Id.* at 370. It is well established that claims must be separately analyzed. *Ex parte Jochim*, 11 USPQ2d 561 (BPAI 1988).

The rejection, however, completely fails to identify or articulate any factual basis or supporting evidence to establish that undue experimentation is required to practice the claimed invention based on Applicants’ Specification. The Examiner asserted only that “[t]he specification does not enable any person skilled in the art to which it pertains ... **since the reference** ... cultures the same microorganism in the presence of substrate(s) within the scope of the claimed subject matter with the same pH, time and temperature but does not produce and recover Vitamin C.” (Paper No. 20070531 at 3) (emphasis added). The Examiner’s observation, however, is not only irrelevant but also falls short. The Examiner failed to present any evidence or reasoning why this observation is relevant to enablement **of this Specification**. There is no evaluation of what one skilled in this art would have understood from what is

disclosed in this Specification. Moreover, there is no attempt to even define what the level of skill in the art was. At bottom, the Examiner's observation, without more, is an impermissible attempt to shift the burden to the applicant to positively establish enablement.

As is well known, burden-shifting of this kind is not allowed. "In order to make a rejection, ***the examiner has the initial burden*** to establish a reasonable basis to question the enablement provided for the claimed invention.... ***[T]he minimal requirement is for the examiner to give reasons*** for the uncertainty of the enablement. ***This standard is applicable even when there is no evidence in the record of operability without undue experimentation beyond the disclosed embodiments.***" MPEP § 2164.04 (8th ed. Rev. 5, August 2006, p. 2100-191) (emphasis added). Thus, the rejection falls short of the kind of analysis and evidence required to establish a *prima facie* case for lack of enablement. For this reason alone, the rejection should be withdrawn.

We further note that even a "considerable amount" of experimentation is permissible if it is merely routine or if the specification provides a reasonable amount of guidance. MPEP § 2164.05 and *In re Wands*, 8 USPQ at 1404. Indeed, it is well recognized that "a patent need not teach, and preferably omits, what is well known in the art." MPEP § 2164.01 (8th ed. Rev. 5, August 2006, p. 2100-187) *citing In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v.*

American Hoist & Derrick Co., 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

Here, the Specification contains three examples that include detailed descriptions of the reaction conditions for the claimed process for producing Vitamin C. Moreover, the Specification at, for example, page 3, lines 16-21 identifies those reaction conditions:

The cultivation can be conducted at a pH of 4.0 to 9.0, wherein a pH value of about 5.0 to 8.0 is preferred. The cultivation period varies depending on the pH, temperature and nutrient medium to be used, and is preferably about 1 to 5 days, most preferably about 1 to 3 days. The preferred temperature range for carrying out the cultivation is from about 13° C to about 36° C, more preferably from 18° C to 33° C. A preferred result is obtainable from an incubation which utilizes a liquid broth medium.

One skilled in the art would clearly recognize from the specification and Examples 1-3 the reaction conditions which produce Vitamin C by the currently claimed process.

Moreover, the Examiner's assertion that "[t]he specification does not enable any person skilled in the art to which it pertains ... since the reference ... cultures the same microorganism in the presence of substrate(s) within the scope of the claimed subject matter with the **same** pH, time and temperature but does not produce and recover Vitamin C" is factually **wrong**. (Paper No. 20070531 at 3) (emphasis added). The Example cited to by the Examiner in U.S. Patent Publication No. 20010026933 refers to an incubated time of 1.5 hours (see para. [0098]), whereas the pending specification indicates, *inter alia*, a cultivation time of, e.g., 4, 20, 24, or 45 hours or 1 to 5 days (see, e.g., Specification at page 3, lines 16-21 and Examples 1-3). This factual error further undermines the rejection. Accordingly, the rejection is factually

insufficient to support a rejection for lack of enablement, and for this reason also, the rejection should be withdrawn.

Notwithstanding the foregoing and with a view toward furthering prosecution, independent claims 1 and 2 have been amended to recite reaction conditions such as pH, time, and temperature. Specifically, claims 1 and 2 now recite "cultivating a microorganism ... at a pH in the range of about 4.0 to about 9.0 and in a temperature range from about 13°C to about 36°C for about 1 to about 5 days" Accordingly, the rejection has been rendered moot and should be withdrawn.

Clearly, the Examiner has not analyzed the claims separately, as required. Not surprisingly, the identified basis for the rejection does not cover the subject matter recited in claims 6 and 10. Accordingly, the rejection is *per se* inapplicable to these claims, and for this reason also, the rejection of claims 6 and 10 should be withdrawn.

In sum, the specification and knowledge in the art provide ample guidance to allow one of skill in the art to practice the claimed invention without undue experimentation. Accordingly, the rejection is factually insufficient to support a rejection for lack of enablement, and for this reason also, the rejection should be withdrawn.

In view of the foregoing, it is respectfully submitted that the rejection has been rendered moot. Accordingly, withdrawal of the rejection is respectfully requested.

Application No.: 10/528,893

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Accordingly, for the reasons set forth above, entry of the amendments, withdrawal of the rejection, and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on September 10, 2007.

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